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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,802	09/10/2003	Patrick Fogarty	TOSK-007CON	5245
24353 7590 09/10/2007 BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			EXAMINER MONTANARI, DAVID A	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 09/10/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/659,802

Applicant(s)

FOGARTY, PATRICK

Examiner

David Montanari

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11, 13-15, 18, 27, 31 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 13-15, 18, 27, 31 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/12/07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicants arguments and amendments filed 6/12/2007 have been entered.
2. The 35 USC 112, first paragraph rejection has been withdrawn.
3. Claims 11, 13-15, 18, 27, 30, 31 and 34 are examined in the instant application.

### ***Claim Objections***

Claims 11, 13 and 14 are objected to because of the following informalities: claims 13 and 14 recite the phrase “vector comprises a transposase domain”. However this phrase is unclear. This claim language would imply that a vector comprises a protein, however the specification is clear that the vector comprises a “transposase encoding domain”, which comprises nucleotides. See paragraph 0024 first sentence “In certain embodiments, the subject vectors further include a transposase encoding domain, i.e., a region of nucleotides having a sequence that encodes a protein having transposase activity”. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11, 13-15, 18, 27, 31 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,291,243 B1 (Fogarty et al.)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Fogarty et al. teach and claim a method of inserting an exogenous nucleic acid into a non-insect target cell genome using a P element derived vector (claim 12). The P element derived vector comprises a pair of P element transposase recognition sites flanking at least two non-insect cell transcriptionally active expression modules each comprising a coding sequence and a promoter (claim 1). The P element vector taught by Fogarty et al. further comprises that said transposase recognition sites are 31 base pair inverted repeats (claim 6). Fogarty et al. teaches that the P element vector comprises an inter P element domain that is at least 50 bp in length, or usually at least 1000 bp in length corresponding to the nucleic acid to be inserted into the host genome (col. 4 lines 1-11). This teaching by Fogarty anticipates that a single transcriptionally active gene is separated from a P element transposase domain by a distance of about 1000 bp or less. The claims in the 243' patent are drawn to a method of using a P element vector that comprises at least two non-insect cell genes flanked by a pair of P element transposase recognition sites, however Fogarty et al. in their specification teach that a single gene can be flanked by said transposase recognition sites (col. 5 lines 5-9). Fogarty et al. explicitly states that " Vectors of this embodiment that include a single transcriptionally active gene may be prepared and used as described below, where the following description is provided in terms of vectors that

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include at least two transcriptionally active genes.” (col. 5 lines 5-9). Fogarty et al. further teach that the P element vector can be used to insert exogenous or endogenous nucleic acids into the genomes of mammalian cells including rat and murine (col. 5 lines 42-59). Fogarty et al. further teach that a second vector can be delivered using the claimed method (claim 14). With regard to the claimed rodent made by the claimed method, the prior art is enabling to the extent that a transgenic mouse is created using the claimed method and the method disclosed in the 243’ patent. Fogarty teaches that the claimed method, which is a transformation method, can be used for the creation of transgenic animals, including rodents (col. 1 lines 16-28). Thus Fogarty et al. clearly anticipate the claimed method.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108.


The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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